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| 10/756,269      | 01/14/2004  | George M. Halow      | A-8051.CIP.RNFMP/bh | 2686             |

7590 09/22/2006

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EXAMINER

CHOI, FRANK I

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1616

DATE MAILED: 09/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/756,269

Applicant(s)

HALOW, GEORGE M.

Examiner

Frank I. Choi

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Examiner withdraws the finality of the prior Office Action in order to apply additional grounds of rejection

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1-41 indicate that the compositions and methods do not contain additional electrolytes for counterbalancing electrolyte loss during use. However, the amount and type of electrolytes are not claimed and/or disclosed and the intended use of the additional electrolytes is not material for purposes of a composition claim. The claims 32-35 indicate that the compositions can be combined with clear liquid diet powders, flavor packs and/or other adjuvants, such as flavor packets, dietary powders such as powder bouillon or herbal preparations. According page 7 of the Specification, it the patient receives a sufficient amount of liquids containing sodium and potassium ions to satisfy hunger, no supplemental electrolytes need be used with the PEG/phosphate compositions. As such, the Specification suggests that the liquid diet powders, flavor pack and other adjuvants contain electrolytes which then can be added to the PEG/phosphate composition. As such, the discussion on page 2 of the Specification

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that related art purgatives normally include electrolytes to counterbalance electrolyte loss during treatment is not sufficient to support a negative limitation excluding the same from the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention as follows:

As indicated above, the amount and type of electrolytes are not claimed and/or disclosed and the intended use of the additional electrolytes is not material for purposes of a composition claim in the negative limitation which excludes additional electrolytes for counterbalancing electrolyte loss. As such, the addition of any amount or type of electrolytes would appear to read on the negative limitation. As indicated above, one or more of the dependent claims when viewed in light of the Specification add back electrolytes which were excluded by the negative limitation. As such, the claims are inconsistent and indefinite.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO

98/43654 in view of Cleveland et al. (US Pat. 6,048,901), Di Palma et al., Wood et al. (US Pat.

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5,498,425), Vining (US Pat. 5,782,762), Matsuoka et al., Sobrino-Faya et al. and Physician's Desk Reference (49<sup>th</sup> Ed. 1995).

WO 98/43654 teach a composition and method of purging the colon prior to colonoscopy, radiographic examination or bowel surgery containing sodium phosphate salts, including mono and dibasic salts) combined with polyethylene glycol, bisacodyl and cascara sagrada and that the composition can be administered in solid or liquid (aqueous) form (Pgs. 1, 7, 11). It is taught the combination of compounds are present in amounts effective to produce a purgative and/or laxative composition and that one of ordinary skill in the art may readily determine the amount and types of compounds/compositions to used in treating a particular patient (Pg. 11).

Cleveland et al. teach that polyethylene glycol is effective in reducing intestinal gases, cramping and/or anorectal irritation associated with constipation and which can be exacerbated by use of laxatives (Column 1, lines 14-30). It is taught that the composition is preferably substantially free of ancillary electrolytes as salts may exert a constipative effect (Column 45-58). It is taught that the PEG polymer used is solid at room temperature and soluble with water and may be mixed with water or juice (Column 1, lines 58-68, Column 2, lines 1-20).

Di Palma et al. disclose that the use of PEG-3350 without use of electrolytes as are present in Golytly® and Nulytely® at 68 g and 85 g resulted in complete evacuation within 24 hours and 51 g of PEG-3350 resulted in 80% evacuation within 24 hours and concludes that the investigation provides data concerning PEG 3350 efficacy for eliciting a rapid, limited action (Pages 1778-1779). It is disclosed that there were no changes in measured electrolytes, calcium, glucose, BUN, creatine or serum osmolality (Page 1777). It is disclosed that the doses are

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considerable lower than those used in combination with the balanced electrolyte solutions for GI cleansing; a 4-L cleansing dose of SF-ELS has 420 g of PEG 3350 (Page 1776).

Wood et al. ('425) teach that cascara and bisacodyl are used for bowel clearance. It is taught that powders may be packaged in aluminum lined paper containers and that such packets are economical and easier to ship and store (Column 1, lines 6-12, Column 3, lines 4-7).

Vining teaches that in addition to using laxatives the patient should be put on a clear liquid diet to obtain a clean bowel for examination (Column 8, lines 1-20).

Matsuoka et al. disclose the combination of 45 ml of oral sodium phosphate (Fleet®) mixed with 45 ml of water and 1000 ml of PEG electrolyte lavage which was tolerated well and resulted in satisfactory cleansing of the colon (Abstract). It is disclosed that this modified method using smaller amount of oral lavage is useful in the preparation for colonoscopy (Abstract).

Sobrino-Faya et al. discloses the combination of 90 ml of a standard preparation of sodium phosphate with 1500 ml of PEG and that colonic cleansing tended to be better with sodium phosphate and PEG versus sodium phosphate alone (Abstract).

Physician's Desk Reference (1995) discloses that 5 ml of regular or flavored Fleet® Phospho®-soda contains 2.4 g of monobasic sodium phosphate and .9 g of dibasic sodium phosphate and that 45 ml is used as a purgative (Pgs. 1018, 1019).

The prior art discloses the combination of sodium phosphate and PEG for evacuating the bowl for colonoscopy. The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the combination sodium phosphate and PEG for use as a bowel cleanser which does not contain additional electrolytes for counter-balancing electrolyte

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imbalance. However, the prior art amply suggests the same as the prior art discloses the combination of PEG and sodium phosphate for use as a bowel cleanser and that PEG –3350 can be used without the electrolytes present in Golytely® and Nulytely ® without there being changes in measured electrolytes. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the combination of PEG and sodium phosphate would be effective as a bowel cleanser for use in clearing bowel prior to examination procedures and would not require the use of electrolytes as in used in Golytely® and Nulytel® and would require a considerable lower dose than the balanced electrolyte solutions for GI cleansing.

The examiner has duly considered Applicant's arguments but deems them unpersuasive.

The claims purport to exclude additional electrolytes for counterbalancing electrolyte imbalance, however, the dependent claims 32-35, allow electrolytes to be added back into the composition by addition of powders, flavor powders and other adjuvants. As such, whether the electrolytes are originally included or added when used in combination with powders or liquids that contain electrolytes, the result is the same as the prior art compositions and methods. Further, WO 98/43654 as indicated above does suggest the combination of sodium phosphate salts with PEG without mentioning that electrolytes would be required. Thus, the negative limitation does not appear to overcome the rejection herein. Also, Applicant has not shown the criticality of the amounts of phosphate salt and PEG used, as such, the fact that the same exact range of amounts are not disclosed does not overcome the rejection. One of ordinary skill in the art would be able to vary the amounts used depending on efficacy in evacuating the bowel. The examiner notes that contrary to Applicant's assertion in the response to the Advisory Action

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(8/1/2006), the criticality of the amounts of PEG and phosphate salt are not a new grounds of rejection as it was Applicant who raised the issue in the response to the final office action (See Remarks (5/9/2006), page 10). Applicant has argued that the amounts of sodium phosphate in the prior art are higher than that used in the claimed invention. However, Applicant has not provided any evidence of the same. The claims are directed to percent weight, as such, the claims include any amount of sodium phosphate and any amount of PEG so long as the sodium phosphate makes up 10-50% by weight and PEG makes up 50-90% by weight of the combination of both.

The examiner has duly considered both Declarations of Inventor Halow (4/5/2005, 8/3/2006). The fact that the Sobrion-Faya and Matsuoka references disclose a PEG solution that contains electrolytes does not overcome the rejection. The combined teachings of the prior art disclose that PEG can have a quick laxative effect without the use of electrolytes, that ancillary electrolytes can be constipative and that at the doses used there were no changes in measured electrolytes. As such, one of ordinary skill in the art would expect that the combination of sodium phosphate and PEG would be effective in evacuating the bowel and not require the use of electrolytes or large volumes as are used in the balanced electrolyte solutions for GI cleansing such as Golytely® or Nulytely®. Also, the comparative tests were against Golytely® and Fleet® which were used each alone and at full dose. However, the prior art discloses that the combinations of a standard preparation of sodium phosphate with 1000-1500 ml of PEG solution, albeit with electrolytes, were well tolerated. As such, the comparative data does not appear sufficient to overcome the rejection herein.

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Applicant has argued that there is no motivation to select PEG from the list set forth in WO 98/43654. However, WO 98/43654 clearly indicates that sodium phosphate can be combined with PEG to cleanse the colon, as such, this provide motivation to combine sodium phosphate with PEG. See *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945) ( "Reading a list and selecting a known compound to meet known requirements is no more ingenious than selecting the last piece to put in the last opening in a jigsaw puzzle." 325 U.S. at 335, 65 USPQ at 301.). Since no mention is made of using electrolytes with PEG, one of ordinary skill in the art would have been motivated to simply combine the sodium phosphate with PEG which would meet the requirements of the negative limitation. Further, Cleveland provides an additional motivation to avoid the use of additional electrolytes as said electrolytes can be constipative. This constipative effect would be counter-productive to the desired laxative or purgative effects. Because the constipative effect is the reason that Cleveland discloses the avoidance of ancillary electrolytes, Cleveland, contrary to Applicant's arguments, does not teach away from the claimed invention. However, the prior art discloses the use of sodium phosphate salts for cleansing the colon, as such, one of ordinary skill in the art would not include sodium phosphate salts as being excluded by Cleveland et al. since sodium phosphate salts clearly do not have a constipative effect. Di Palma et al. also provides motivation to use PEG with use of balanced electrolyte solutions as PEG without the same was shown to provide a rapid bowel cleansing effect without changes in electrolyte measurements.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-41 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30, 32, 33, 35, 36 of copending Application No. 10/194251. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims 1-30, 32, 33, 35, 36 of the '251 application anticipate claims 1-36 of the present Application in that the '251 application claims amount ranges of the same components which fall within the ranges in the present application. Claims 37-41 are obvious of the claims of the '251 application in that the '251 application discloses amount ranges of the sodium phosphates and amount ranges of PEG which falls within the range of the PEG in the present claims. The difference between the claims of '251 application and the claims of the present invention is that the PEG is water-soluble and in a dry dosage form which is subsequently dissolved in water for use, whereas the claims of the present Application claim a PEG which liquid at room temperature and is in a liquid dosage form which optionally can be combined with an aqueous medium. However, it is well within the skill of one ordinary skill in the art to modify the prior art as above with the expectation that when the '251

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application composition is dissolved in an aqueous medium for use, the PEG contained therein will be liquid at room temperature. As such, claims 37-41 are an obvious modification of the claims of the '251 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### *Conclusion*


A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Thursday, Friday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Dr. Johann Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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September 14, 2006

  
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